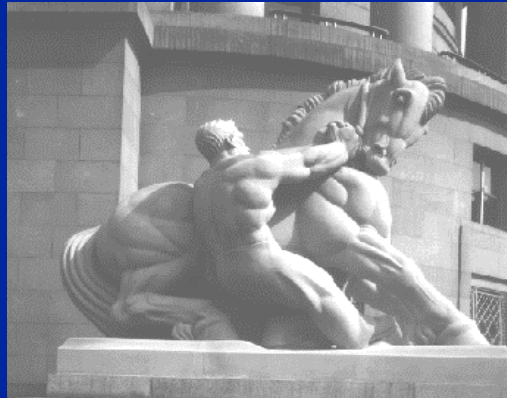


Genetic Testing:

The Role of the FTC



Matthew Daynard

Division of Advertising
Practices

*The views expressed by Mr. Daynard are his
and do not represent those of the Commission or
individual Commissioners*

Overview

- Jurisdiction
- Advertising Principles
- FTC & Privacy
- Project Cure.All--HIV Home Test Kits
- Industry/Consumer Education

FTC Jurisdiction

Federal Trade Commission Act

- Unfair or deceptive acts or practices prohibited (15 U.S.C. 45(a))
- False advertisements for foods, drugs, devices, and services prohibited (15 U.S.C. 52)
- Includes marketers of genetic tests/Ad Claims

Definitions

Deceptive: a representation, omission, or practice is *deceptive* if (1) it is likely to mislead consumers acting reasonably under the circumstances; and (2) it is material; that is, likely to affect consumers' conduct or decisions with respect to the product at issue.

Definitions

Unfair: a practice is unfair if the injury to consumers it causes or is likely to cause (1) is substantial; (2) is not outweighed by countervailing benefits to consumers or to competition; and (3) is not reasonably avoidable by consumers themselves.

Definitions

False Advertisement: an advertisement is false if it is misleading in any material respect (taking into account not only representations made, but also the extent to which the advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the product or service).

FTC-FDA Liaison Agreement

- Since 1954, agencies have operated under a formal agreement which provides that:
 - ◆ FTC has primary jurisdiction for the advertising of foods (including supplements), OTC drugs, devices and cosmetics;
 - ◆ FDA has primary jurisdiction for the labeling of the products and for both advertising and labeling of prescription drugs by manufacturers

Ad Claims vs. Practice of Medicine

- True and substantiated health claims are an important part of the FTC mission
- Injury to consumers can be serious should they use the wrong product/service or forego other treatment
- FTC actions after the AMA and Goldfarb Supreme Court cases
- Actions addressed business and advertising practices, not the practice of medicine
- We do not regulate how doctors use or prescribe drugs/devices/services in treating patients or other choice of therapy issues.

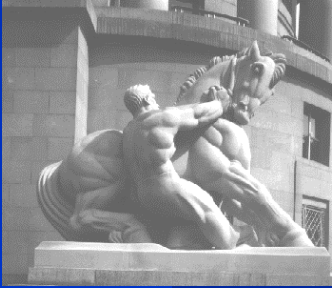
Basic Advertising Principles

- **Tell the truth:** don't mislead consumers about the benefits or safety of your product by what you say expressly or by what your ad implies
- **Tell all the truth:** don't omit information that is needed to keep what you say from being deceptive
- **Make sure it is the truth:** do have adequate support for any objective claim (express or implied) before you run the ad



Claims/Ad Meaning

- Advertisers are responsible for express and reasonably implied claims
- Net impression of ad is important
 - ◆ text, product name, visual images
- Disclose qualifying information if necessary to prevent deception
- Disclosures must be clear and conspicuous



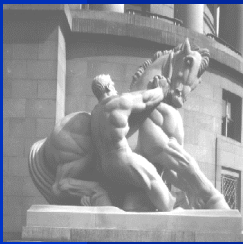
Substantiation

- Must have support for claims before disseminating ad
- Standard is flexible
 - ◆ depends on claim: how presented, how qualified
 - ◆ ensures consumer access to information about emerging science/service
 - ◆ ensures that information is accurate
- Standard is rigorous: “Competent and Reliable Scientific Evidence”
 - ◆ consult with experts in wide variety of fields



Amount and Type of Evidence

- No fixed formula
- What experts in field would consider adequate
- Well-controlled human clinical studies are best
- Anecdotal evidence is not adequate
- Quality more important than quantity



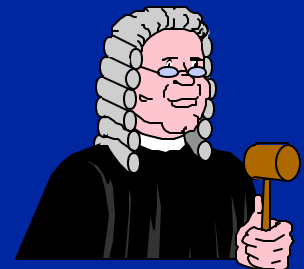
Quality of Evidence

- No specific protocol
- Factors that contribute weight to evidence:
 - ◆ control and blinding
 - ◆ duration (as evidence that effect persists)
 - ◆ dose/response (cause-effect) relationship
 - ◆ peer review/publication in reputable journal
- Results should be statistically significant and clinically meaningful
- Foreign studies should meet accepted research norms



Totality of the Evidence

- Studies cannot be evaluated in isolation
- Consider all relevant evidence
- Check for inconsistent or conflicting results
- Carefully qualify evidence to accurately reflect the strength of science
- Don't make even qualified claims, if weight of evidence runs contrary to claim





Relevance of Evidence to Claim

- Research must be relevant to service and benefit being advertised
 - ◆ protocol being used
 - ◆ differences that might alter effect
 - ◆ characteristics of population
- Make sure claim matches science
 - ◆ don't exaggerate degree/nature/permanence of effect
 - ◆ don't mischaracterize certainty of science



Consumer Testimonials/ Expert Endorsements



- Unsubstantiated claims can not be made indirectly through testimonials
- Testimonial = representative experience
 - ◆ if not, must disclose the typical experience, or that consumers should not expect to achieve those results
 - ◆ “results may vary” is inadequate disclosure



MD/Expert Endorsements

- Increasing concern about physician endorsements for unsubstantiated claims
- Expert endorsers must be qualified, evaluate the service, and independent – (material personal or financial connection to advertiser must be disclosed)

MD/Expert Endorsements

- Claims must be substantiated
- FTC has brought cases against MDs in the past
 - ◆ *Numex Corp.*, 116 FTC 1078 (1993)
 - ◆ *Synchronal Corp.*, 116 FTC 989 (1993)
 - ◆ *Patricia Wexler, M.D.*, 115 FTC 849 (1992)

MD/Expert Endorsements

■ Orders:

- ◆ Prohibit doctors from making false or unsubstantiated claims or endorsements
- ◆ Require actual exercise of expertise in the form of an examination or testing of the product/device as least as extensive as an expert in the field would normally conduct to support the conclusions presented



Third Party Literature

- FTC does not regulate the content or accuracy of books, articles, or non-commercial literature
- FTC does prohibit the deceptive use of such materials in advertising

“All parties who directly or indirectly market health care services/dietary supplements have an obligation to make sure that claims are presented truthfully and to check the adequacy of the support behind those claims.”

FTC's Privacy Initiative

- Public Workshops since 1995
- Surveys of commercial Websites
- Annual reports to Congress since 1998
- Fair Information Practice Principles
 - ◆ Notice, Choice, Access, Security,
(Enforcement)
- Law enforcement actions
- Education of consumers and businesses

Privacy & Genetic Testing

- 93% of consumers in a recent survey opposed the use of an individual's genetic information for research without prior consent

– Gallup Survey, August, 2000

Privacy: Section 5 Law

Enforcement Actions (e.g.)

■ Geocities

- ◆ Settled charges Web site misrepresented purposes for which it was collecting PII from children and adults

■ Liberty Financial Companies, Inc.

- ◆ Challenged allegedly false representations on “Young Investors” site that information collected from children in an online survey would be maintained anonymously

Online Pharmacy: Privacy

- *FTC v. Rennert, et al.*, No. CV-S-00-0861 JBR (D. Nev. filed July 6, 2000)
- Represented to consumers that the information customers provided would be encrypted and that defendants use an SSL secure connection when transmitting this information over the Internet –
- Represented that they would use personal information only for medical consultations and billing for prescriptions and consultations –

Online Pharmacy: Privacy Order

- Order prohibited these representations and required defendant to:
 - Establish and maintain reasonable procedures to protect the confidentiality, security and integrity of personal information collected from consumers;
 - Provide reasonable means by which a consumer may access and review personal information;
 - Provide reasonable means by which a consumer may modify inaccurate personal information or delete personal information

Pharmacy Order: Privacy Policy

- Clear and conspicuous disclosure of privacy policy covering
 - Type of personal information obtained
 - Use of information and choices available to consumers
 - Means of access to information
 - Means to modify or delete information
 - Measures employed to ensure security



FTC Privacy Resources

- www.ftc.gov/privacy
- www.ftc.gov/kidzprivacy
- www.consumer.gov

Operation Cure.All

Operation Cure.All uses consumer and business education and law enforcement to target deceptive and misleading online marketing of products and services being promoted as cures or treatments for serious diseases. Participants include the FTC, FDA, and several States.

Cure.All Mission

- Primary goals:
 - ◆ Help consumers find truthful/accurate health information
 - ◆ Teach consumers how to distinguish legitimate health products from health scams
 - ◆ Protect vulnerable consumers from injury (economic and health)
 - ◆ Foster growth of internet commerce

Operation Cure.All

- Two FTC health claims surf days in fall of 1997 and 1998.
- 1998 Surf:
 - ◆ 80 organizations; 25 countries (Canada & Mexico)
 - ◆ Search for treatment/cures for cancer, arthritis, heart disease, AIDS, diabetes, MS
 - ◆ Epidemic of health fraud on Internet: 400 sites in one afternoon of surfing; some therapies, devices; vast majority was supplements



Operation Cure.All

- **E-mail advisories:** Of 400 sites receiving FTC warning in 1998, 28% responded by removing claims or disappearing.
- **Consumer Education:**
 - ◆ *www.ftc.gov* provides links to many reliable sources of health information (e.g. Healthfinder.Gov; NCCAM; ODS)
 - ◆ “Virtual Treatments,” “Fraudulent Health Claims” provide tips on spotting scams.
 - ◆ “Teaser” sites like “Arthriticure”; “Virility Plus”

HIV Home Tests

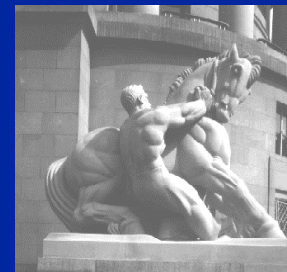
- *FTC v. Cyberlinx, Inc. and Jeffrey S. Stein* (Civ.Act.#CV-S-99-1564-PMP-LRL) (November 1999) (Nevada) (Stipulated Order)
- Defendants falsely represented that their HIV home test kits accurately detected HIV
- Order bans defendants for life from marketing any HIV home test kits; defendants must pay back the money they received from the sale of their kits; and, if they sell other medical devices, they are required to post a \$500,000 bond.

HIV Home Tests

- *FTC v. Medimax, Inc. and David Rothbart* (99-1485-CIV-ORL-99A) (Florida, Middle Dist.) (Stipulated Order) (April 2000).
- *FTC v. Alfa Scientific Designs, Inc.* (00 CV 81 BTM NLS) (So. D. Cal.) (Stipulated Preliminary Injunction) (Jan. 2000) (Medimax supplier).

Industry/Consumer Education

- Advertising Guidelines on www.ftc.gov
 - ◆ Online: Rules of the Road
 - ◆ Dietary Supplements
 - ◆ Refractive Surgery
- “Facts for Consumers”
 - ◆ Diet, Health & Fitness
 - ◆ “Basik Lasik”



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